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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,106	09/28/2000	Randal K. Buddington	2343-104-27	8636

7590 08/25/2005

Patent Prosecution Services  
Piper Marbury Rudnick & Wolfe LLP  
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Washington, DC 20036-2412

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/671,106

**Applicant(s)**

BUDDINGTON ET AL.

**Examiner**

Simon J. Oh

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 04 August 2005.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 27, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Each rejected claim has been amended to designate inulin as a sole pharmaceutically active ingredient. However, it is unclear where such a claim limitation draws support from the specification. Furthermore, the table on Page 14 that illustrates the composition used in the examples lists several ingredients that are pharmaceutically active, including vitamins and salts. Even sucrose can arguably fall within the bounds of pharmaceutically active substances. Since a definition of the term "pharmaceutically active ingredient" is not found in the specification, the examiner will rely on a definition of the term that is commonly accepted.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-46 under 35 U.S.C. 103(a) over Paul *et al.* and Van Loo *et al.* is maintained.

***Response to Arguments***

Applicant's arguments filed 04 August 2005 have been fully considered but they are not persuasive.

As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." As the compositions in both prior art references have similar various effects which are known in the art to be beneficial to a subject, one of ordinary skill in the art would have a reasonable chance of success in combining the two references. Such effects include a reduction of intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism (See Paul *et al.*, Columns 2, 3, and 7-11; and Van Loo *et al.*, Column 2).

Furthermore, the Paul *et al.* patent discloses that the compositions disclosed therein promote the growth of beneficial bacteria, which lowers the intestinal pH, which then inhibits the overgrowth of gastrointestinal pathogens. Hyper-proliferation of harmful bacteria in the gastrointestinal tract is associated with increased susceptibility to systemic infections (See Paul *et al.*, Column 10, Lines 13-

Art Unit: 1618

22 and 37-45). The examiner will therefore broadly interpret this disclosure as reading on the treatment of systemic infections. At the very least, there is now an established link between gastrointestinal health and the likelihood of being afflicted with a systemic infection. All claims will therefore remain rejected.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

sj0

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